REMARKS

Reconsideration of this application is respectfully requested. The courtesy of the Examiner during an interview on March 23, 2004, is appreciated.

New claims 55 through 63 have been added directed to a method for filtering blood support for the new claims is in the specifications at, for example, page 28, Ins. 9-17 and page 31, Ins. 1 to page 3, ln. 7.

I. Interview Summary

The Examiner's written interview summary is correct. During the interview, applicants submitted a proposed set of amended claims which is the same as the amended claims set forth above. However, a limitation has been added, at the suggestion of the Examiner, to claim 27 regarding the surface area of the filter membrane. A similar filter surface area limitation was included in amended claim 1 as proposed during the interview.

As discussed during the interview, several of the limitations recited in the claims are supported in the specification with an explanation of the significance of the limitation to the invention.

- Filter membrane surface area of 0.2 m^2 or less is a relatively small filter area as compared to much larger filters typically used in dialysis systems for adults. *Compare* Spec. p. 20 ("filters used for CVVH in adults have the membrane surface area of 0.7 – 2 m^2) *to* p. 32, ln. 23 to p. 33, ln. 5 ("Applicants did this by drastically reducing the filter membrane surface

area compared to common dialysis or CVVH filters to maintain high shear rate and low blood residence time. Specifically, a filter with the membrane surface of less than 0.2 m^2 ").

- Blood flow through filter is less than two percent of total cardiac output. This limitation relates to the relatively low blood flow withdrawn and filtered. *See* Spec. p. 29, lns. 13-15. The Specification states that in conventional central access systems that rely on large filters and blood circuits that hold a relatively large volume of blood, e.g., as much as 10% of total cardiac output. *See* Spec. p. 13.
- Filtrate removal of 1.0 liters or less also defines a low blood flow system, as compared to conventional continuous veno-venous hemofiltration (CVVH) systems. *Compare* Spec. p. 18, lns. 20-22 (In CVVH, "[l]arge amounts of blood, in the range of 100 – 400 mL/min or as much as 10% of the total cardiac output for an adult patient, are passed through the filter") *to* p. 29, lns. 12-16 ("Assuming this extraction rate, the amount of blood removed from a peripheral vein is less than 2% of the total cardiac output. In addition, at this extraction rate, the potential ultrafiltrate flow may be as much as 1 L/hour.").
- Control of the blood flow in the circuit based on withdrawal and/or infusion pressure. *See e.g.,* Spec p. 25, lns. 5-15 and p. 26, lns. 18-16. Control based on withdrawal and/or infusion pressure is particularly useful when

the blood tubes of the circuit are narrow and/or the veins accessed by the circuit are peripheral veins that easily become occluded. In contrast, the large tubes used to access a central vein of prior systems are much less likely to occlude.

II. Response To Rejections

In view of the second restriction requirement, claims 1 to 4, 6 to 15 and 17 to 48 have been elected. Claims 5 and 16 have been cancelled without prejudice.

The rejection of claims 7 and 33 as being indefinite regarding claiming a natural function of a human kidney has been resolved by cancellation of those claims.

The rejection of claims 1 to 4, 6, 8, 9, 13 to 15, 17 to 32, 34, 35, 39 to 42 and 44 to 48 as being obvious over U.S. Patent 4,828,543 (Weiss) in view of U.S. Patent No. 5,211,849 (Kitaevich) is traversed. The rejected claims are limited to removing blood via access through a blood vessel, controlling the flow rate of the blood based on monitored pressure of the blood flow, filtering the blood to remove fluid, and returning the condensed blood to a blood vessel. Independent claim 1 is limited to peripheral vein access, while claim 27 is not. However, all claims include limitations regarding a reduced blood flow rate(s) that is indicative of peripheral blood withdrawal or withdrawal through relatively small diameter catheters. The claims have been amended to recite that the blood flow rate is controlled based on withdrawal and/or infusion pressure, which is believed to be important to treating blood at the reduced rates that are the subject of the present invention.

Weiss discloses a blood filtering circuit having blood pumps 104,106 and a filter 142. The filter both removes filtrate from the blood and infuses dialysate fluid into the blood. The filter is one that is "typically used in dialysis and other applications." Weiss, col. 11, lns. 38-41. Weiss does not disclose pressure sensors in the withdrawal and/or infusion lines. Rather, Weiss teaches pressure sensors associated with the filter to provide TMP control of the flow through the filter.

Kitaevich also discloses a hemofiltration system. Kitaevich teaches control of a blood circuit based on the weights of the infusate supply and of the filtrate (drain). Kitaevich, col. 3, lns. 15-25. Based on the weights of these supplies, Kitaevich controls the infusate and filtrate pumps. Pressure sensors are merely used in Kitaevich to stop the pumps if certain pressure levels are transversed. Kitaevich, col. 6, lns. 31-35.

Weiss and Kitaevich do not suggest applying the withdraw and/or infusion pressure to control the rate of blood flow through a blood circuit. Accordingly, these references are not well suited for peripheral vein access or low blood flow access.

It is impermissible to ignore the claim limitations regarding blood flow rates through the filter. The rates recited in the claims, e.g., less than 1.0 liters per hour, are contrary to the prior art teachings of higher flow rates of 4 to 1.0 liters per hour, Spec., page 18. Reducing the withdrawal flow rate is contrary to the prior art which teaches high blood flow rates for conventional blood treatment therapies.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone the undersigned. Prompt reconsideration and allowance of this application is requested.

Respectfully submitted,

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